

Product Statement

Products: Nunc Immuno Modules, BreakApart, PolySorp
Raw materials: Polystyrene, PS (65927)
SAN, Acrylnitril-Butadien-Styren-terpolymer (ABS) fiber reinforced (65931)
Polypropylene, PP (69436)

Thermo Fisher Scientific hereby confirms that the above-mentioned products have been designed and are manufactured from selected materials.

The material (Polystyrene) has successfully passed the following test:

- USP <88> "Biological Reactivity Tests, In Vivo" class VI:
- Biological evaluation of medical devices – ISO 10993-5, tests for in vitro cytotoxicity. The cell line used is L-929 (mouse connective tissue)
- USP <87> "Biological Reactivity Tests, In Vitro, Elution test"

Inspection point of the products:

Visual control according to our quality inspection procedures and specifications.
Test of function according to our quality inspection procedures and specifications.

The expiry date is manufacturing date plus 5 (five) years.

Quality assurance of the products are performed in accordance with the requirements of the Quality Management System ISO 9001:2008 "Quality management system – Requirements" and ISO 13485:2003, "Medical devices – Quality management systems – System requirements for regulatory purposes".

Roskilde Site

Signature: Maria Elisa Rex
Maria Elisa Rex, QA coordinator

Date: 2016-11-15
(YYYY-MM-DD)